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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,899

07/13/2006

Raviraj S. Pillai

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

11/27/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/585,899	Applicant(s) PILLAI, RAVIRAJ S.	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-13-06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims included in the prosecution are 1-19.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The dependent claims 3 and 4 recite, "further comprises" followed by 'fatty acid esters'; since fatty acid esters are also lipids, the examiner suggests define the lipid in the independent claims 1 and 15 to render claims definite.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 8, 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Betageri (US 6,759,058) of record.

Betageri discloses microparticles containing a lipid core and a poorly water-soluble active agent and an enteric coating containing hydroxypropyl methylcellulose

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phthalate. The composition in addition contains compounds such as polyethylene glycol (plasticizer or solubilizing agent) (abstract, col. 3, line 5 through col. 4, line 13 and examples).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan (US 5,614,222) of record.

Kaplan teaches microspheres having a lipid core containing the active agent, which are enterically coated with hydroxypropyl methylcellulose phthalate. The lipids include fatty acids (surfactants), fatty acid esters, waxes and mixtures thereof. The enteric coating includes coloring agents and agents, which retain a desired texture (plasticizer) (abstract, col. 4, line 39 through col. 6, line 30, Examples).

6. Claims 2, 9 and 10 lack an inventive step under PCT Article 33(3) as being obvious over BETAGERI cited above.

The teachings of BETAGERI have been discussed above. What are lacking in is the claimed amount of the active agent or the solubilizing agent and the claimed payload. However, the amount of the active agent is deemed to be a manipulatable parameter since it depends upon the condition of the disease and other parameters. Similarly, in the absence of showing unexpected results, the amount of the solubilizing agent and the payload are deemed to be manipulatable parameters.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan cited above in view of Hendrick (US 5,356,644).

The teachings of Kaplan have been discussed above. What is lacking in Kaplan is the teaching of the preparation of the microspheres using centrifugal co extrusion method.

Hendrick et al while disclosing microspheres containing a core and a solid fat coating teach that they can be prepared by centrifugal co extrusion process col. 4, lines 33-38 and claims).

It would have been obvious to one of ordinary skill in the art to prepare the microspheres of KAPLAN using centrifugal co extrusion process with a reasonable expectation of success since the reference of Hendrick et al shows that it is routinely used for preparing coated microspheres.

9. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan cited above in view of Hendrick (US 5,356,644) as set forth above, further in view of Eichel et al (5,238,686).

The teachings of Kaplan and Hendrick et al have been discussed above. What is lacking in these references is the teaching of hardening the microspheres using an

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acid bath.

Eichel et al while disclosing sustained release preparations containing an enteric coating teach the microcapsules can be hardened by the reduction of pH below 5.5 using inorganic acids which are then washed and dried (abstract and col. 6, lines 28-42).

Immersing the microspheres of Kaplan in an inorganic acid bath would have been obvious to one of ordinary skill in the art since such a process would harden the microspheres as taught by Eichel et al.

The references are all of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore /
Primary Examiner, Art Unit 1612

GSK